STRATEGIC ISSUES SERIES

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THE CHALLENGE OF BIOTECHNOLOGY & PUBLIC POLICY

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The views in this discussion paper are those of the author and do not represent the views or positions of the Department of Justice, Canada. The paper was commissioned as an opinion piece to stimulate research and discussion.

Strategic Issues Series

The Research Papers included in the Strategic Issues series generally have been prepared for the Statistics and Environmental Analysis Unit of the Research and Statistics Division (RSD). This series is part of the Research and Statistics Division's efforts to look ahead and to scan the environment to provide contextual facts and perspectives on a wide range of social and economic issues. Topics covered include: the policy challenges of bio-technology and genetics; speculation on markets for crime and a proposed typology for understanding crime; the impacts on children of divorce and separation; globalization; and global governance of the Internet.

The papers that will be included are thought-provoking. In general they have been written by academics whose commission instructed them to be wide-ranging in their critique of current practices and provocative in their suggestions for new approaches.

Discussion papers and think pieces in this section of the RSD library have already stimulated discussion for exercises such as: new mandate planning, strategic policy planning by senior executives or as backgrounders for research planning. It is our intention to offer them here so that they now can contribute to wider discussion among researchers and policy-makers.

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Biography

Bartha Maria Knoppers, Canada Research Chair in Law and Medicine, is Professor at the Faculté de droit, Université de Montréal, Senior Researcher (C.R.D.P.) and Counsel to the firm of Borden Ladner Gervais. She is a graduate of McMaster University, (B.A.), University of Alberta (M.A.), McGill University (LL.B., B.C.L.), Cambridge University, U.K., (D.L.S.), Sorbonne (Paris I) (Phd.) and was admitted to the Bar of Quebec in 1985.

Currently, Chair of the International Ethics Committee of the Human Genome Organization (HUGO), she was a member of the International Bioethics Committee of the United Nations, Educational, Scientific and Cultural Organization (UNESCO) which drafted the Universal Declaration on the Human Genome and Human Rights (1993-97). She is Co-Founder of the International Institute of Research in Ethics and Biomedicine (IREB) and Co-Director of the Quebec Network of Applied Genetic Medicine (RMGA). In 1999, she became a member of the Canadian Biotechnology Advisory Committee, and in the year 2000 of the Board of Genome Canada.

In October 2001 she received a Doctor of Laws honoris causa from the University of Waterloo and in February 2002 was elected Fellow by the American Association for the Advancement of Science.

1.0 Introduction

While at first glance genetic choices will largely be private, prospective and preventive, their cumulative effect is not without public implications.

The next decade will be characterized by three developments: the proliferation of genetic choice, the emergence of complex systems, and, an increasing public concern and interest in the definition of what is "human". While at first glance genetic choices will largely be private, prospective and preventive, their cumulative effect is not without public implications. Furthermore, rapid progress in the genomic life sciences (animal, plant, human) together with informatics are contributing to the emergence of highly dynamic complex systems of information gathering, storage and management, systems difficult to characterize and control. These developments have raised a certain sense of public unease with the deciphering of the genomes of all living organisms (human/plant/animal) and a perceived transgression of our humanness, if not humanity, in this new technocracy.

To understand, analyze and project on the need for a public policy framework as epigenetic as the subject matter and social trends it would seek to address, requires a preliminary understanding of how these three developments: choice, complexity, and, concepts of humanness will emerge.

Developments in both genetics and genomics have attracted a tremendous amount of media attention. Less immediately evident but equally important are the effects on future generations.

2.0 Human Genetics

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Current sequencing and mapping efforts in the human genome project foresee completion by the year 2003 or earlier. Creating much hope in the power of both sophisticated diagnostic and prognostic tools, and of informatic capabilities within medicine, the new "post-mapping" genetic medicine promises: 1) genetic screening of asymptomatic populations for carrier status and prevention of onset of genetic conditions; 2) knowledge of susceptibility status for specific and individualized drug targeting; and 3) genetic testing for individual treatment, reproductive and lifestyle choices. All this can occur prior to embryo implantation, or, during infancy, adolescence and adulthood. Until specific genetic markers are found for a given condition however, most genetic information in the post-mapping era will still come from the contribution of familial pedigrees, forcing the reconstruction of the biological "genetic" family, partially abandoned today in favor of consensual, social family forms.

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In short, expression of personal choices based on risk estimates will only become more certain and thus personally significant as basic genetic epidemiological research advances. Paradoxically, hindrances to such population data research for fear of possible misuse or misunderstanding while perceived to be protective of personal privacy and intimacy undermine transparency and public oversight in that they drive informatics and genetic research into the private sector. While the public has accepted bio/data banking as useful for criminal surveillance of morally reprehensible activities, no such acceptance exists for the creation and promotion of population data banking (be it genetic samples or information). It is precisely this lack of basic scientific data at the level of populations that will exacerbate current discrimination based on lack of knowledge.

Indeed, the use of inaccurate and thus unscientific information will have several untoward effects. Firstly, workplace and insurance screening based on actuarial data will be inaccurate. Lack of large population data bases will create an inability to prove such inaccuracy and thus, inadvertently foster illegitimate uses. Secondly, any decision to integrate genetic information into public health, planning, promotion and prevention programs at the level of the State will either be thwarted for fear of public opinion or again be unscientific and thus, unethical. Thirdly, these population database systems could, if promoted and used in a transparent way, not only be subject to public surveillance but also contain the very checks and balances needed to conform to modern privacy goals (legitimacy, authentification, transparency, finality,...). Thus, we need to prepare new ethical frameworks for genetic epidemiology that while inspired by individualistic ethics and sensitive to communitarian ethics (the concerns and cultural concepts of "collectivities"), address the urgent need for an appropriate methodology specific to population health.

3.0 Genomics

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Genomics goes well beyond human genetics in that it concerns all living organisms. New life sciences companies manipulate "life" for therapeutical and environmental properties. They span basic research to the clinical and industrial applications of DNA-based technologies, to the culture and reproduction of plants and animals and include the study of pharmaceutical properties. Such "biotic" possibilities place all of living

organisms into research and permit the study of homologies and differences between the species. Ultimately, transgenic "pharming" will not only produce plants and animals that carry vaccines and that have therapeutic properties but also the development of tissues or even organs transferable to humans (xenotransplants). These life science industries promise "biotic" possibilities of increased productivity, of resistance to adverse events, and the development of nutraceuticals. Concerns for the preservation of species integrity and biodiversity have placed these life sciences at the forefront of public debate. Classical approaches to the safeguarding of ecosystems may no longer be sufficient. As we co-evolve and co-adapt with the plant and animal species, the natural environment itself presents new viruses for which we have no treatment (e.g., BSE in animals; the new variant of Creutzfeld-Jakob in humans). Together then genetics and genomics will transform life in its pure biological form and in its lived human forms. Are humans then just another form of living matter in this new biotic universe?

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4.0 The "Humanity" of Future Generations

The creation of this knowledge and its possible (ab)uses, will affect future generations as well. Personal and collective ethics will need to reflect an understanding of the transgenerational effects and the accompanying new and different obligations. Such obligations may or may not include deliberate interfering in the germ line for example in order to avoid the transmission of a given disease to the next generation. The globalization of science, of economies and of information take transgenerational concerns beyond the domestic to an international scale. Similarly, bioethics must move from the private, to the collective, to a truly universal level. A complex systems approach that recognizes the dynamic and epigenetic nature of a new BIOethics at the very level of the cell in all living organisms needs to be encouraged.

The last half of this century has seen the development of bioethics as a form of questioning personal values and the relationship of humans to each other and to the environment and this particularly in quality of life choices. Confronted with new biotechnological and informatic possibilities, such ethics continue to stress respect for individual autonomy and privacy. In the medical setting both the principles of do not harm and maximizing benefit over risk have predominated decision-making. Only in the last few years has attention turned to questions of distributive justice, of equity and more recently, of relational or communitarian ethics but not yet to transgenerational ethics. Likewise, human rights has moved beyond individual claims (civil or economic rights) to encompass the concerns of groups, populations and communities. Confronted then with the new genomic revolution and the personal and collective choices it presents, whither public policy?

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5.0 Policy Framework

Over the last two decades, whether it be organ transplants, reproductive technologies, or human genetics, four approaches are emerging. Briefly introduced, the broad ambit of a constitutional, human rights approach serves to circumscribe the applications of new technologies that otherwise might encourage discriminatory or stigmatizing practices. In contrast, a "statutory-specific" approach crafts laws issue by issue to address the implications of scientific advances through prohibitions, constraints or moratoria. A third possibility is an administrative, regulatory approach concentrating on quality assurance, standardization and monitoring either through governmental or professional bodies. Finally, a liberal, market-driven approach maintains that proper, professional practices will ultimately "win-out" and in any event, all new technologies are subject to the restraining impact of litigation.

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Put concisely, there are advantages and disadvantages to all four approaches. The constitutional approach relies on already existing human rights instruments to interpret the applications of new technologies. These policy-oriented decisions of high ranking courts are strengthened by the intervenor status often afforded to public interest groups, and so serve to express public values, clarify the issues and set far-reaching precedents. Yet, ad hoc in nature and achieved after a given technology has already been integrated into research and health care, the process is a costly and lengthy one and if the court is timorous and refuses to go beyond the facts or issues, a limited recourse.

A statutory-specific method has the advantage of immediate certainty, clarification and precision as well as being an expression of political consensus. The danger remains however, of limited scope and impact beyond the immediate issues, of the closing of public debate and so of encouraging complacency. Finally, if such statutes are adopted in rapid succession, there is a risk of contradictory positions and definitions.

In contrast, a regulatory-standardization approach allows for the gradual development of professional codes of conduct and where necessary, licensing, monitoring and quality assurance through regulation pursuant to already existing broad health legislation. Professionally and procedurally oriented, it ensures a "buy-in" by those involved resulting in greater effectiveness and integration into practice. This incremental approach however has its own drawbacks. It "administers" technologies and fails to explicitly enunciate the value-choices underlying their acceptance or, explain why certain constraints are placed on access, use, or of certain forms of research in the codes or standards themselves.

Finally, the liberal, market place approach has been called the most flexible and promoting of scientific research. Technological development is dependent on investment and support is either public or private. Investment is subject however to lobbying by narrow interest groups, including those who stand to gain financially from

public investment and/or lack of public control, and those who, for a variety of reasons, see certain technologies as potentially harmful or in conflict with their particular values. The inability of these groups to achieve compromise in the broader public arena inhibits the consensus necessary for successful government initiated oversight, thus leaving development of any given technology to the vagaries of the market, the chilling effect of litigation and consumer choice.

The choice between these approaches, or a mix thereof, depends not only on the degree of public trust in the credibility and effectiveness of such tools, but on the state of the debate.

6.0 Conclusion

[T]he current lack of visibility and transparency on the contentious, fundamental quality of life issues constitutes an affront to Canadian citizens... The intermingling of facts and values can only be legitimately recognized and remedied by putting into place procedural mechanisms such as regional fora, media debates, websites and public referenda, etc. that are both participatory and consultative.

Currently, the state of the debate in Canada is that there is no debate, at least not public debate. While not usurping the legitimate role of politicians and governmental policymakers in the framing of policy and in leading the decisional process, the current lack of visibility and transparency on the contentious, fundamental quality of life issues constitutes an affront to Canadian citizens. Our collective moral failure to address these issues in a structured and rational process is the ultimate proof of tunnel vision.

This failure to actively inform and consult the public cannot be remedied by simply providing more information. Scientists themselves while responsible for the production of the knowledge cannot be solely accountable for the (ab)uses of ensuing technologies. While increasingly sensible to the social implications of their work, they must be free to actively and creatively pursue knowledge. Furthermore, greater public trust in the outcomes and direction of scientific research and in the regulatory system is severely hampered by the "dread factor" that is a perceived lack of control and of ongoing oversight of the consequences of such scientific freedom and innovation. Public perception of risk even when not objectively substantiated should not be ignored. The intermingling of facts and values can only be legitimately recognized and remedied by putting into place procedural mechanisms such as regional fora, media debates, websites and public referenda, etc. that are both participatory and consultative. The failure of Bill C-47 on reproductive and genetic technologies was due to its highly prohibitive and criminal law approach. This is symptomatic of bureaucratic ideology presuming what the public wants or what the public needs.

The personal and political cost of engaging in an ongoing open dialogue with the nation will be high. There is no doubt that much courage and patience will be called for, especially in the early phases where the public adjusts to a more democratic process and strident advocates polarize the initial debate. Abdicating such responsibility to the

scientists or simply cleaning up or compensating or legislating post hoc however, will only further undermine public trust in the political process to say nothing of the credibility of our nation's leaders and governments.

Biotechnology and BIOethics cross party lines and provincial and national boundaries to say nothing of genomes and generations. The challenge is to construct a framework and a process that is equally dynamic.

Public policy means just what it says – public and policy-oriented. Beginning with the premise that the great majority of citizens are morally responsible beings with an interest in their society, in scientific advances and in the future of humanity, the specter of "exposure" to that same public should not be frightening. After the first round of polemic and phobia will come a clarification of the facts. After such clarification will come a more sensible and balanced debate respecting diversity and difference especially in a multicultural nation such as Canada. After a more public and transparent airing of the facts and issues, after the provision of information by neutral government sources and the media, two choices remain: the Swiss model of public referenda (free from party politics) when public opinion considers it necessary, or, a healthy parliamentary debate based on a free vote. Biotechnology and BIOethics cross party lines and provincial and national boundaries to say nothing of genomes and generations. The challenge is to construct a framework and a process that is equally dynamic.